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April 9, 2008

VIA FACSIMILE

The Honorable Jack B. Weinstein
United States District Court for the
Eastern District of New York
Brooklyn Courthouse
225 Cadman Plaza East
Brooklyn, NY 11201

Re: *In Re Eli Lilly And Company Securities Litigation*
Civil Action No. 1:07-CV-01310-JBW

Dear Judge Weinstein:

I write to advise Your Honor that the Second Circuit has affirmed the district court's opinion in *In re GlaxoSmithKline PLC Securities Litigation*, No. 05 Civ. 3751, 2006 WL 2871968 (S.D.N.Y. Oct. 6, 2006), which defendants cited in support of their pending motion for summary judgment and to dismiss. (*See* Defs.' Opening Br. at 9 n.30, 12 n.13, 75 n.298, 83 n.319; Defs.' Reply Br. at 6 n.11, 6 n.14, 16 n.52, 17 n.53, 17 n.54, 20 n.74, 22 n.78, 24 n.83, 38 n.149.) Although the Second Circuit issued its Summary Order on March 26, 2008, the day before Your Honor heard oral argument on defendants' motion, we did not learn of the decision until this week.

In its Summary Order, *Masters v. GlaxoSmithKline* (hereinafter "*GlaxoSmithKline*"), No. 06-5140-CV, 2008 WL 833085, at **1-3 (2d Cir. March 26, 2008) (summary order), a copy of which is attached, the Second Circuit affirmed the district court's dismissal of three of the plaintiff's four Rule 10b-5 claims on statute of limitations grounds.[1] While the Court's Order does not have precedential effect (*see* Second Circuit Local Rule

[1] The Court also affirmed the district court's dismissal of the fourth claim for failure to adequately plead materiality and loss causation. *Id.* at **3-4.

§ 0.23),[2] it nonetheless reflects the prevailing Second Circuit law that Rule 10b-5 claims are time-barred and must be dismissed under Rule 12(b)(6) or Rule 56 where publicly available information discloses facts sufficient to have placed a reasonable investor of ordinary intelligence on inquiry notice more than two years before suit was filed.

For these reasons, the Second Circuit's Order affirming the district court's decision in *GlaxoSmithKline* provides additional authority for the granting of defendants' motion for summary judgment.

Respectfully,

Robert L. Hickok

RLH:jmd
Enclosure

cc: Jay W. Eisenhofer, Esquire
Michael K. Yarnoff, Esquire
(both w/encl. via fax and U.S. mail)

[2] Second Circuit Local Rule § 0.23(c)(1) permits citation to summary orders entered after January 1, 2007, so long as the citation is accompanied by the notation "(summary order)" and a copy of the summary order is submitted with the brief or other paper in which it is cited.

Masters v. **Glaxosmithkline**
C.A.2,2008.
Only the Westlaw citation is currently available.This case was not selected for publication in the Federal Reporter.Not for Publication in West's Federal Reporter RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO SUMMARY ORDERS FILED AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY THIS COURT'S LOCAL RULE 0.23 AND FEDERAL RULE OF APPELLATE PROCEDURE 32.1. IN A BRIEF OR OTHER PAPER IN WHICH A LITIGANT CITES A SUMMARY ORDER, IN EACH PARAGRAPH IN WHICH A CITATION APPEARS, AT LEAST ONE CITATION MUST EITHER BE TO THE FEDERAL APPENDIX OR BE ACCOMPANIED BY THE NOTATION: "(SUMMARY ORDER)", UNLESS THE SUMMARY ORDER IS AVAILABLE IN AN ELECTRONIC DATABASE WHICH IS PUBLICLY ACCESSIBLE WITHOUT PAYMENT OF FEE (SUCH AS THE DATABASE AVAILABLE AT HTTP://WWW.CA2.USCOURTS.GOV), THE PARTY CITING THE SUMMARY ORDER MUST FILE AND SERVE A COPY OF THAT SUMMARY ORDER TOGETHER WITH THE PAPER IN WHICH THE SUMMARY ORDER IS CITED. IF NO COPY IS SERVED BY REASON OF THE AVAILABILITY OF THE ORDER ON SUCH A DATABASE, THE CITATION MUST INCLUDE REFERENCE TO THAT DATABASE AND THE DOCKET NUMBER OF THE CASE IN WHICH THE ORDER WAS ENTERED.Summary orders prior to January 1, 2007 are subject to additional limitations. See Fed. Rule of Appellate Procedure 32.1 generally governing citation of judicial decisions issued on or after Jan. 1, 2007. See also Second Circuit Rule U.S.Ct. of App. 2nd Cir. s 0.23, 28 U.S.C.A. (Find CTA2 Rule 0.23)

United States Court of Appeals,Second Circuit.

Joseph J. MASTERS, Plaintiff-Appellant,
Jack Reynolds, On behalf of himself and all others similarly situated, Plaintiffs,
Nancy Harvold, Michael P. Hailperin, Consolidated-Plaintiffs,
v.
GLAXOSMITHKLINE, Jean-Pierre Garnier, Defendants-Appellees,
Smithkline Beecham Corporation, Defendant.
No. 06-5140-CV.

March 26, 2008.

Timothy J. Burke, Stull, Stull & Brody (Jules Brody, on the brief), Los Angeles, CA, for Plaintiff-Appellant.
Andrew J. Levander, Dechert LLP (Steven B. Feirson, Michael L. Kichline, Neil A. Steiner, Scott A. Thompson, on the brief), New York, NY, for Defendant-Appellees.

Present SONIA SOTOMAYOR, REENA RAGGI, Circuit Judges, and CAROL BAGLEY AMON, District Judge.[FN1]

FN1. The Honorable Carol Bagley Amon, United States District Court for the Eastern District of New York, sitting by designation.

SUMMARY ORDER

PRESKA, J.
***1** UPON DUE CONSIDERATION of this appeal from the judgment of the United States District Court for the Southern District of New York (Preska, J.), it is hereby ORDERED, ADJUDGED, AND DECREED that the judgment is AFFIRMED.

Lead plaintiff-appellant Joseph Masters challenges the district court's dismissal of his second amended putative class action complaint (the "complaint") alleging securities fraud claims under Section 10(b) of the Securities Exchange Act and Rule 10b-5 against defendant-appellants GlaxoSmithKline PLC ("GSK"), and its Chairman and Chief Executive Officer, Jean-Pierre Garnier.[FN2] We review the district court's grant of defendants' Rule 12(b)(6) motion to dismiss *de novo,* and accept as true all allegations in the complaint and draw all reasonable inferences in favor of Masters. *See Vietnam Ass'n for Victims of Agent Orange v. Dow Chemical Co.,* 517 F.3d 104, 2008 WL 465825, at *8 (2d Cir. Feb.22, 2008).

FN2. The district court also dismissed

> Masters' additional claim that Garnier was liable as a control person of GSK under Section 20(a) of the 1994 Act. Masters has waived any challenge to the dismissal of this claim on appeal. *See* Norton v. Sam's Club, 145 F.3d 114, 117 (2d Cir.1998).

The complaint alleges that GSK violated the Exchange Act in four ways: (1) by making false statements and omissions regarding the viability of GSK's patents for its drugs Paxil and Augmentin, and engaging in a course of frivolous litigation with respect to those patents (the "Patent Claim"); (2) by suppressing information about Paxil's addictiveness and withdrawal effects (the "Paxil Withdrawal Claim"); (3) by violating the Federal False Claims Act by overcharging Medicare and Medicaid for GSK's pharmaceutical products, resulting in multiple lawsuits against GSK (the "Overcharge Claim"); and (4) by misrepresenting the safety and efficacy of the use of Paxil in children and adolescents (the "Paxil Pediatric Claim").

The district court dismissed all but the Paxil Pediatric Claim on statute of limitation grounds. Section 804 of the Public Company Accounting Reform and Investor Protection Act of 2002 ("Sarbanes-Oxley"), extended the statute of limitations period applicable to section 10(b) of the Exchange Act and Rule 10b-5 to the *earlier of* "(1) two years after the discovery of the facts constituting the violation; or (2) 5 years after such violation."28 U.S.C. § 1658(b). The two-year limitations period-referred to as the "inquiry notice" period-is triggered when " 'circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded.'" *LC Capital Partners LP v. Frontier Ins. Group Inc.*, 318 F.3d 148, 154 (2d Cir .2003) (quoting *Dodds v. Cigna Securities, Inc.*, 12 F.3d 346, 350 (2d Cir.1993)).

Although the triggering of inquiry notice is an issue "often inappropriate for resolution on a motion to dismiss," where "the facts needed for determination of when a reasonable investor of ordinary intelligence would have been aware of the existence of fraud can be gleaned from the complaint and papers ... integral to the complaint, resolution of the issue on a motion to dismiss is appropriate."*Id.* at 156 (internal quotations and citations omitted); *see also* Dodds, 12 F.3d at 352 n. 3. For the reasons below, we agree with the district court that, based on the allegations in the complaint, Masters was on inquiry notice with respect to the Paxil Withdrawal, the Patent, and Overcharge Claims no later than two years prior to when he filed his original complaint on April 12, 2005; thus, these claims were untimely.

***2** With respect to the Paxil Withdrawal Claim, in August 2001, GSK was sued in class action lawsuits by consumers of Paxil claiming adverse effects upon ceasing Paxil's use, and related fraudulent behavior by GSK, news of which was made available not only in the press but also in GSK's 2001 year-end Form 20-F filing with the Securities Exchange Commission ("SEC").[FN3] Further, Masters alleges that the disclosure of the lawsuits caused a drop in the price of GSK's securities on September 6, 2001. Moreover, in December 2001, GSK after consulting with and securing approval from the Federal Drug Agency ("FDA"), changed the labeling of Paxil to include a warning about its discontinuation effects. Masters' assertions that the foregoing disclosures were not adequate "storm warnings" to trigger inquiry notice are meritless. *See LC Capital,* 12 F.3d at 154.Notwithstanding Masters' assertion that the class actions did not allege claims of fraud, the complaints in the class actions sufficiently made known the underlying factual allegations forming the basis of Masters' securities fraud claim. *Cf.* Menowitz v. Brown, 991 F.2d 36, 42 (2d Cir.1993). In addition, notwithstanding Masters' assertion that the warning label approved by the FDA itself mischaracterized or understated the full extent of Paxil's alleged withdrawal effects, the warning label was not the type of "reassuring statement [ ]" that might allay a reasonable investor's concern. *See LC Capital,* 318 F.3d at 155. Accordingly, the Paxil Withdrawal Claim was properly dismissed as untimely.

> FN3. The relevant portion of this Form 20-F was not in the record but was annexed to GSK's reply brief before the district court. Masters has no objection to our consideration of this document. As we are not relying on any other publically available filings that were not in the record, we need not address Masters' objection to our consideration of the publically available documents submitted to us by GSK post-argument.

So was the Patent Claim. No later than March 2002,

GSK announced that at least one court had invalidated certain of GSK's patents covering Augmentin. Moreover, in July 2002, GSK announced that it had lost one patent case involving Paxil, and in December 2002, announced that it was having mixed results in other litigation over its patents. Meanwhile, in July 2002, the Federal Trade Commission made public a report that was critical of GSK's conduct in pursuing its Paxil patent. In addition, the complaint alleges that GSK stock price dropped numerous times between March 13, 2002 and March 4, 2003 in response to developments in the patent litigation.

Masters' assertions that the limitations period was not triggered because the trial courts' patent decisions were on appeal, and because the price declines in GSK's securities were not sufficiently "sharp" to put an investor on inquiry notice, are unavailing. We have held that district court filings and opinions may suffice to trigger the limitations period, *LC Capital*, 318 F.3d at 155;*Menowitz*, 991 F.2d at 42, and we are aware of no case requiring a certain degree of price decline before the limitations period may commence, especially where, as here, there were multiple drops in price. Equally unavailing is Masters' reliance on Garnier's statements in the press that "We are very confident we can defend our patents[,]" and "we feel that the courts eventually will recognize the letter of the law and give us the added protection for Augmentin."As the district court found, these statements were not the type of "reassuring words" that might negate inquiry notice, *see* *LC Capital*, 318 F.3d at 155; rather, they were of a type a reasonable investor would view as mere expressions of hope. Accordingly, the Patent Claim was untimely.

***3** The Overcharge Claim fares no better. The complaint acknowledges that lawsuits were filed against GSK starting in November 2001 as a result of its alleged violations of the False Claims Act, and that public disclosure of these lawsuits caused GSK's share price to decline on December 11, 2001. We reject Masters' claim that it was the settlement of the litigation in April 2003 that triggered inquiry, rather than the filing and reporting of the litigation itself. *See, e.g.*, *LC Capital*, 318 F.3d at 155 (knowledge of a lawsuit may be sufficient to trigger inquiry notice); *Menowitz*, 991 F.2d at 42 (same). Thus, the district court properly dismissed all but the Paxil Pediatric Claim as untimely under 28 U.S.C. § 1658(b).[FN4]

FN4. Because we affirm the district court's dismissal of the Paxil Withdrawal, Patent, and Overcharge Claims on statute-of-limitation grounds, we do not reach the district court's alternative bases for dismissing these claims.

But that remaining claim fails on other grounds; namely, a lack of materiality and failure to allege loss causation. With respect to materiality, section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security ... any manipulative or deceptive device or contrivance" in violation of SEC rules and regulations. 15 U.S.C. § 78j(b). The SEC implementing rule, Rule 10b-5, prohibits the making of untrue material statements of fact or the misleading omission of material facts in connection with the purchase or sale of securities. 17 C.F.R. § 240.10b-5. An omission is material only if there is "a substantial likelihood that the disclosure of the omitted fact could have been viewed by the reasonable investor as having significantly altered the 'total mix' of information available."*Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 357 (2d Cir.2002) (internal quotations and citations omitted).

Masters complains that GSK violated 15 U.S.C. § 78j(b) and Rule 10b-5 by not timely disclosing allegedly adverse results of certain research trials, and by sponsoring researchers to publish false and misleading materials, concerning the safety and efficacy of Paxil for treatment of children and adolescents. We have held that reports of harmful drug effects are immaterial-and thus need not be disclosed-unless those reports (1) show statistically significant evidence of an adverse effect, (2) establish that the adverse effect threatens the "commercial viability" of the drug; and (3) show that the effect poses a significant risk to the company's future earnings. *In re Carter-Wallace, Inc. Securities Litig.*, 150 F.3d 153, 157 (2d Cir.1998); *accord* *Oran v. Stafford*, 226 F.3d 275, 284 (3d Cir.2000). The complaint does not explain how the results of the research trials at issue could be deemed statistically significant in light of the test results from another trial that GSK did disclose.

Even assuming that the non-disclosed test results were statistically significant, they were financially immaterial. The same is true with respect to the

alleged misstatements by those who were allegedly sponsored by GSK. According to the complaint, less than 3% of GSK's revenues from Paxil came from prescriptions to children because the drug was neither FDA-approved nor directly marketed for that use. The potential loss of that small amount of "off-label" sales did not threaten the commercial viability of Paxil, much less pose a significant risk to the total future earnings of GSK, which sold several other drugs in addition to Paxil. *See In re Carter-Wallace*, 150 F.3d at 157;*cf. Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52 (2d Cir.1995) (affirming dismissal of plaintiffs' securities fraud claim where alleged omission affected less than 1% of defendants' total products); *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 547 (8th Cir.1997) (finding alleged 2% overstatement of assets immaterial in light of company's financial prospects).

***4** The district court cases relied upon by Masters are inapposite, as each involved a development stage company that failed to disclose negative studies that threatened not only the product's commercial viability, but also the company's viability. *See, e.g., In re Regeneron Pharms., Inc. Sec. Litig.*, No. 03 Civ. 3111, 2005 WL 225288 (S.D.N.Y. Feb. 1, 2005); *In re Sepracor, Inc., Sec. Litig.*, 308 F.Supp.2d 20 (D.Mass.2004); *In re Viropharma, Inc. Sec. Litig.*, No. 02 Civ. A 1627, 2003 WL 1824914 (E.D.Pa. Apr. 7, 2003). Accordingly, we affirm the district court's dismissal of the Paxil Pediatric Claim for failure to adequately allege materiality.

In addition, the complaint fails as a matter of law to allege loss causation with regard to the Paxil Pediatric Claim. *See Dura Pharm. Inc. v. Broudo*, 544 U.S. 336, 342-43, 347, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005) (explaining that a securities fraud plaintiff must demonstrate "a causal connection between the material misrepresentation and the loss"). Although the complaint alleges two stock losses, on June 24, 2004 and December 9, 2004, Masters fails to demonstrate a casual link between these alleged losses and the alleged misconduct. The price prior to the first negative market reaction was $42.77, while the price after the second negative market reaction was $44.82, or $2.05 higher, and Masters pleads no facts supporting a conclusion that he was nevertheless adversely affected. *Id.* at 347 (concluding allegation of inflated purchase price alone insufficient to plead relevant loss causation). Moreover, as GSK points out, the December 9, 2004 stock drop occurred after the close of the class period and thus cannot be relied upon for loss causation. Accordingly, the Paxil Pediatric Claim was properly dismissed for failure to plead loss causation as well.[FN5]

> FN5. Because we affirm the district court's dismissal of the Paxil Pediatric Claim for failure to adequately allege materiality and loss causation, we do not reach the district court's alternative basis for dismissing this claim.

Finally, we reject Masters' claim that the district court abused its discretion in dismissing the complaint without granting leave to amend. *See*Fed.R.Civ.P. 15(a); *see also Ellis v. Chao*, 336 F.3d 114, 126-27 (2d Cir.2003). Prior to filing this complaint, Masters was "directed to serve a consolidated amended complaint, [d]efendants' were to advise [Masters] of perceived deficiencies, i.e., grounds for motion to dismiss, and [Masters] was given the opportunity to file a second amended complaint with the understanding that no further amendments would be permitted."The district court, in dismissing the complaint, did not abuse its discretion in holding Masters to his side of the bargain. That is especially so given the lack of any indication that the complaint's shortcomings could be cured by amendment. *See Yerdon v. Henry*, 91 F.3d 370, 378 (2d Cir.1996) ("Where it appears that granting leave to amend is unlikely to be productive, it is not an abuse of discretion to deny leave to amend.").

C.A.2,2008.
Masters v. Glaxosmithkline
Slip Copy, 2008 WL 833085 (C.A.2 (N.Y.))

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